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**LANCET NEEDLE ANCHOR AND METHOD**

**FIELD OF THE INVENTION**

The present invention relates to lancets which are lancing devices primarily used to obtain capillary blood samples for various testing purposes, not the least of which is blood glucose in the case of diabetics where such testing may be done on a daily basis. The purpose of the lancet is to penetrate the epidermis to a sufficient depth in order to draw the necessary amount of blood needed for the test, and yet hold the penetration, scarring, and injury to the epidermis to the irreducible minimum.

**BACKGROUND OF THE INVENTION**

The present invention has, by way of background, various lancing devices which hold the lancet needle, cover, and carrier. One such device is manufactured for ProCare LLC, and is submitted separately in a prior art disclosure. Basically, however, the lancing device contains a sliding barrel with a trigger button and a base support for the lancet. A lancet cover is provided which threadedly surrounds the lancet as it is positioned in the barrel. At the outer end is an adjustable comfort tip with a lancet cover having numerical indicia and an arrow which, by rotation of the cover, determines the empirical depth to which the needle will penetrate.

Virtually all hypodermic syringes have siliconized needles to aid in insertion to reduce the pain of insertion and further penetration. Therefore, it is desirable to siliconize the lancet needle. This permits the needle to be easily dislodged from the lancet body. In addition, a significant amount of plastic is employed by the prior art for such devices to attempt to secure the needle or blade against dislodgement, and protect against dimensional irregularities.

1           Therefore, what is needed is a lancet in which the needle portion is  
2     firmly embedded in the plastic body, secured against rotation, secured against linear  
3     removal, and yet permits the utilization of a minimal amount of plastic, which plastic  
4     may be of an inferior grade and therefore less expensive than most lancet bodies,  
5     while still providing the sanitary and dimensional support necessary.

6  
7                               SUMMARY OF THE INVENTION

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9           The present invention derives from the molding of a lancet body  
10    around a needle or blade, in which the inner end of the needle body which is  
11    unsharpened has an L-shape bend. As a result of the L-shape bend, when  
12    embedded in the plastic which forms the body of the lancet, the needle can neither  
13    rotate nor be removed linearly. In short, the needle is permanently immobilized  
14    against movement within the body of the lancet, within the X, Y and Z directions.  
15    The method of the present invention involves the bending substantially  
16    perpendicularly of the unsharpened end of the needle or blade to be substantially  
17    perpendicular with the elongate body of the blade. The thus formed needle or blade  
18    is placed within a jig interiorly of the plastic mold which is used to form the lancet  
19    body and the cover, with the cover surrounding the entirety of the sharpened portion  
20    of the needle or blade. The jig includes spaced opposed clamps and a single  
21    orienting support to the bent portion of the needle. Also, the body of the lancet is  
22    relieved in many areas and has a molded tab cover thereby reducing the plastic  
23    used and eliminating a loose part such as a separate cover.

24  
25           In view of the foregoing it is a principal object of the present invention  
26    to provide an apparatus and method for forming a lancet in which the needle or  
27    blade is securely positioned against any dislodgement, whether by rotation, or by  
28    linear movement within the lancet body.

29  
30           A further object of the present invention is to provide such a lancet in  
31    which rotation and longitudinal dislodgement are prevented, which can  
32    accommodate a relatively low grade form of plastic and yet present in operation a  
33    dimensionally stable lancet, fully sanitary, for use with the typical user's home  
34    care kit.

1 A further object of the present invention is addressed to a method of  
2 forming a lancet body and needle or blade with a cover head on a highly cost  
3 effective basis attributable to the lack of necessity for special purpose jigs to control  
4 the position of the needle or blade within the lancet body. As a result, a further  
5 objective is achieved by providing the bent leg or L-shaped end portion so that it can  
6 be precisely positioned interiorly in the mold, and the plastic body of the lancet  
7 molded around the needle or blade with the offset anchor resulting in a product  
8 which is dimensionally accurate to tolerances which are acceptable and heretofore  
9 unknown on the quantities produced for the disposable lancet market.

#### 10 11 DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

12  
13 Further objects and advantages of the present invention will become  
14 apparent as the following description proceeds, taken in conjunction with the  
15 accompanying illustrative drawings in which:

16 FIG. 1 is an exploded partially perspective view of a typical home  
17 lancing device showing the lancet in a mid-portion of the figure;

18 FIGS. 2A, 2B, 2C, 2D, 2E, 2F and 2G, show the utilization of the  
19 device typically by the patient applying the lancet to his/her own finger;

20 FIG. 3 is a perspective partially broken exploded view of the subject  
21 lancet showing the needle or blade interiorly thereof in its secured position;

22 FIGS. 4A and 4B are two views of the lancet needle which is molded  
23 into the body portion of the lancet;

24 FIG. 5 is a front elevation of the lancet;

25 FIG. 6 is a side elevation of the lancet;

26 FIG. 7 is a transverse sectional view of the lancet taken at 7-7 of  
27 FIG. 5;

28 FIG. 8 is a plan view, partially diagrammatic and partially broken, of  
29 the lower portion of the mold utilized to form the subject lancet;

30 FIG. 9 is a transverse sectional partially diagrammatic view, in  
31 enlarged scale, taken along section line 9-9 of FIG. 8; and

32 FIG. 10 is yet another transverse sectional view taken from FIG. 8 at  
33 section line 10-10 showing the support for the angled base anchor 26 of the  
34 needle 25.

1                    **DESCRIPTION OF THE PREFERRED EMBODIMENT**

2  
3                    In the preferred embodiment, as illustrated in FIG. 1, the lancing  
4 device 10 is used to obtain a capillary blood sample needed for blood glucose  
5 monitoring or for other tests requiring one or two drops of blood. The adjustable  
6 comfort tip 11 on the lancing device 10 permits choosing the best depth for skin  
7 penetration. As shown, there are five discrete positions 12 which can be utilized by  
8 the self-user.

9  
10                  As shown in FIGS. 2A through 2G, the needle cover 21 is twisted off  
11 of the lancet device 10, the new lancet 20 is thereafter inserted into the lancet  
12 carrier 15, the needle cover 21 is removed thereafter revealing the needle 25, the  
13 lancet lancing device then has the comfort tip 11 placed in position. At this point,  
14 rotation of the adjustable comfort tip 11 offers a plurality of levels of skin penetration  
15 (see FIG. 2E). The user empirically determines which of these is best for his use.

16  
17                  The lancing device 10 is cocked by slowly pulling the slide barrel 14  
18 away from the lancing device cover. A click indicates audibly when the carrier is  
19 locked in position. Thereafter the end of the adjustable comfort tip is pressed  
20 against the finger, the trigger button 16 is engaged, and the lancing device needle  
21 tip sharpened end 28 penetrates the epidermis to a point where the one or two  
22 drops of blood needed can be drawn.

23  
24                  Turning now to FIG. 3, which is an exploded perspective view, it can  
25 be seen that the two principle components of the lancet itself are the body 22 and  
26 the needle cover 21 cap which are the molded portions, and the needle or blade 25  
27 which is the metal portion.

28  
29                  Important to the invention, and particularly shown in FIGS. 3, 5 and 8,  
30 is the configuration of the needle or blade 25 in which the end opposite the  
31 sharpened end 28 has been bent at an angle with the needle body 29. Desirably  
32 the bend is perpendicular to the main body 29. Such a bend to form an anchor 26  
33 critical to the present invention in that, by providing the offset, once the needle is

*Sub A*  
2 ~~molded into the body of the lancet it cannot be moved longitudinally, nor can it be~~  
3 rotated, nor can it be moved sideways in any direction. By virtue of the angled base  
4 anchor **26**, the needle or blade **25** is permanently, dimensionally and sanitarly  
5 positioned inside the lancet body with the needle cover in place but removable by  
6 twisting to dislodge, basically as described in FIG. 3 above. The method of the  
7 present invention will become more apparent as the description of the body **22** of  
8 the lancet proceeds. As can be seen in FIGS. 5 and 6, there are four runners **(30)**  
9 which, in cross-section, give a cruciform appearance, as shown in FIG. 7. There  
10 two uninterrupted runners **31**, and two interrupted runners **32**. The interrupted  
11 runners **31** are formed when the opposed prongs of a vise are positioned in place  
12 interiorly of the mold to securely engage the needle prior to injecting the plastic. In  
13 this fashion the position of the needle is ensured and when the vise elements are  
14 withdrawn from the body **22**, ports are revealed which reduce the amount of plastic  
15 employed, and simultaneously permit the user to see and observe the needle  
16 interiorly of the body **22**.

17 While dimensions and composition materials do not form a key portion  
18 of the invention, those used in a commercial embodiment are illustrative of  
19 successful dimensions. All dimensions are in millimeters. As noticed particularly  
20 in FIGS. 5, and 6 the entire lancet is 32 mm in length. The body portion is 20.7 mm,  
21 plus or minus 2 mm. The thickness dimension, taken from the tips of the runners,  
22 is 6.3 mm.

23  
24 The needle, as shown in FIGS. 4A and 4B, is 24.4 mm in length, plus  
25 or minus 2 mm. The bent leg is 1.8 mm in length taken from the far side of the body  
26 portion. As shown in FIG. 4A, there is double-bevel at the sharpened end **28** of the  
27 needle. The material ideally employed is stainless steel 1CR18NI9.

28  
29 The material employed for the plastic body is LDPE, better known as  
30 "low density polyethylene" blended with HDPE, better known as "high density  
31 polyethylene". Virgin or reground may be used. Runners and flashing are reground  
32 and may be used exclusively or blended with virgin material.

1 While dimensions are not considered critical, they illustrate the  
2 precision involved. The total overall length of the lancet, including the cover,  
3 is 32 mm. The diameter at the largest portion of the body across the top of  
4 opposed runners is 6 mm. The total diameter of the tip or cap portion is 9.4 mm,  
5 and its thickness is 3.5 mm.

#### 6 7 8 THE METHOD

9  
10 The method of the present invention involves developing a mold 34  
11 for a plurality of needles 25 in connection with a multiple cavity mold in which the  
12 needle or blade are positioned so that the same can be an interior portion of the  
13 completed lancet 20 when the plastic is injected into the recess which surrounds the  
14 carrying portion of the bent angle needle or blade. In this connection, it will be seen  
15 in FIG. 5 that the needle body 22 actually shows interiorly of the lancet body 20  
16 because the support which holds the needle is surrounded by plastic, when the  
17 support is removed the needle appears. On the opposite side the needle is similarly  
18 viewed through much smaller ports. The reason for the smaller ports is that they  
19 contain a pin which clamping engages the needle on the post support of the jig  
20 interiorly of the mold to thereby firmly position the needle to be encapsulated in the  
21 plastic which is thereafter molded around the needle or blade.

22  
23 Specifically as shown in FIG. 8, a multiple cavity mold 34 is intended  
24 for forming the lancet 20. As shown here there are 20 cavities, ten on each side.  
25 Specific details of two cavities are shown in the upper right corner of FIG. 8.  
26 Turning now to FIG. 9, it will be seen that a clamping assembly 40 is used to engage  
27 the main body 29 of the needle 25. The lower jaw 41 of the clamping assembly 40  
28 is somewhat larger than the upper jaw 42 of the same clamping assembly. The  
29 needle 25 is positioned on top of the lower jaw 41 prior to molding. At or about the  
30 same time, the angled base anchor 26 of the needle 25 is positioned on top of the  
31 anchor support 44. When the upper portion of the mold is placed over the lower  
32 portion, and the plastic is injected, the needle 25 and its components are securely  
33 held in place by the clamping assembly 40. After the plastic has sufficiently cooled,  
34 the two mold supports are removed and the lancets 20 removed from the mold.

1 Specifically as shown in FIG. 5, it will be seen that the interrupted runners 32 have  
2 ports which remain exposing needle body. The vise ports 35 are large vise ports 36,  
3 and small vise ports 38. In addition, there is an anchor support port 45, viewed  
4 particularly in FIG. 5, and in which the angled base anchor 26 of the needle 25 is  
5 exposed. This results from the withdrawal of the anchor support 44 when the upper  
6 and lower portions of the mold are separated.

7  
8 Summarizing the above, the method contemplates providing a mold  
9 having a plurality of cavities which are the mirror image of the lancet 20 to be  
10 molded. The next step in the process relates to providing clamping means, which  
11 are opposed, and which clampingly engage the needle body at spaced relationship.  
12 Finally, the step includes providing an anchor support at one end whereby the  
13 needle is not only supported on the anchor, but the anchor determines the position  
14 of the point of the needle within the molded lancet body cover. Thus, the  
15 sequencing, once the clamping means are provided within the mold, and the  
16 support means exist for the angled base anchor portion 26 of the needle 25, the  
17 needles are inserted in the one portion of the mold on top of their respective  
18 supports, shown here as three in number (two for the needle body 25 and one for  
19 the angled base anchor 26). Thereafter the mold top is placed on the mold bottom,  
20 the clamping members engage the needle 25 in fixed relationship to the cavity to be  
21 filled with plastic. Once the plastic is within the balance of the cavity, the needle is  
22 positively oriented therein in relation to the base of the needle and the runners  
23 which, in turn, control the spaced relationship of the sharpened end 28 of the needle  
24 or blade 25 when positioned in a typical lancing device 10, such as shown in  
25 FIGS. 1 and 2A through 2G.

26  
27 It will be understood that various changes in the details, materials and  
28 arrangements of parts, or method which have been herein described and illustrated  
29 in order to explain the nature of the invention, may be made by those skilled in the  
30 art within the principle and scope of the invention as expressed in the appended  
31 claims.